BELAIR Study

Bictegravir's Effect on Persistent Low Level Viremia And Immunological Response. BELAIR study: A pilot prospective observational study.



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Background

Real-world experience with low-level viremia (LLV) remains not well-reported and clinical studies evaluating the clinical management and impact of persistent LLV between 50-200 copies HIV-RNA/mL on subsequent emergence of drug resistance and virologic failure (VF) are limited. Co-formulated Bictegravir, Emtricitabine and Tenofovir Alafenamide Fumarate (BIC/FTC/TAF) is recommended as first-line treatment with high genetic barrier for People with HIV (PWH).

Aim of the study

Evaluation of the effect of TAF/FTC/BIC on experienced PWH with persistent LLV.

Statistical Analysis

 IBM Statistical Package for Social Sciences (SPSS), version 19.0 (IBM Corp., Armonk, NY, USA). The normality of quantitative variables was tested with Kolmogorov-Smirnov test and they were expressed as mean ± standard deviation (SD).
 Post-hoc analysis was performed using Sidak's

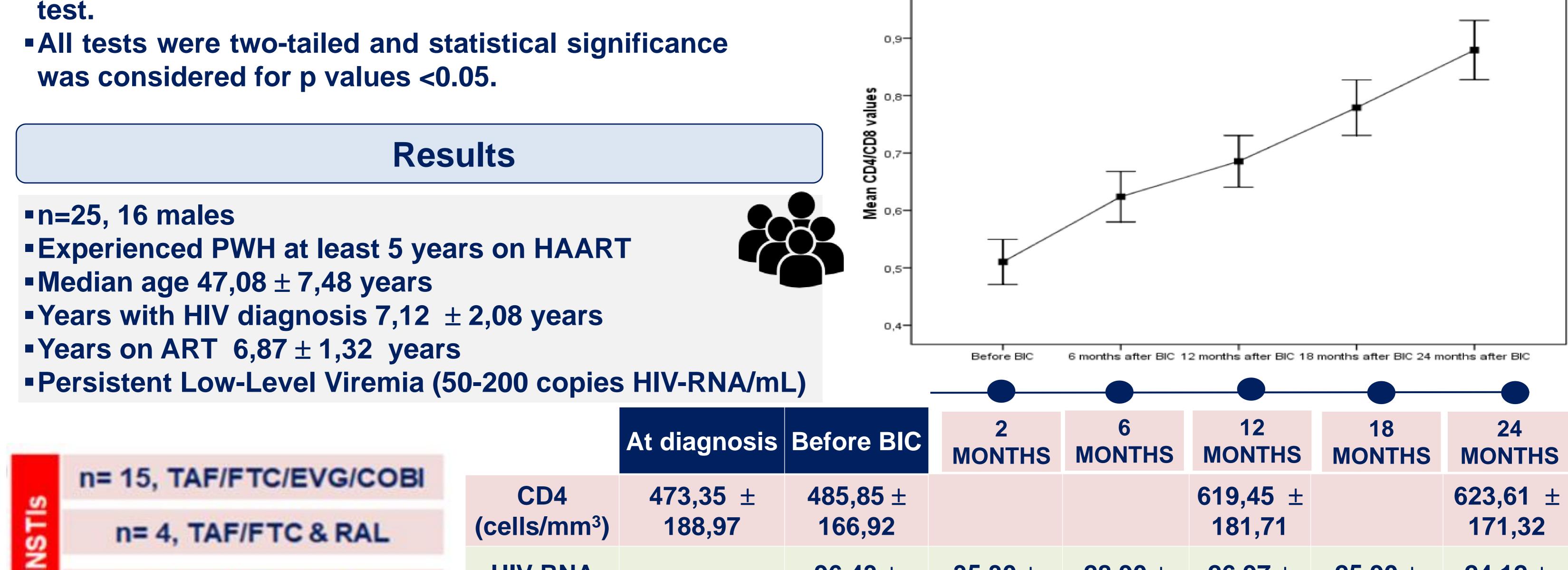
Patients & Methods

Observational Prospective Study during 2022-2024. PWH at least 5 years on HAART included in the study after switch to BIC/TAF/ FTC. Demographic (age, gender) and clinical data (transmission mode. CDC stage, with HIV diagnosis, years on the study of the stage).

mode, CDC stage, years with HIV diagnosis, years on HAART, treatment before switch, CD4 cell count and HIV-RNA at diagnosis) were reported from the patients' medical records.

 CD4 cell count, CD4/CD8 ratio and HIV-RNA were evaluated 2, 6, 12, 18 and 24 months after the BIC/TAF/FTC initiation.

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| n= 1, TAF/FTC & DTG | HIV-RNA (copies/mL) | 96,43 ± 37,25 | 35,30 ± 32,16 | 28,90 ± 23,57 | 26,97 ± 18,12 | 25,90 ± 17,73 | 24,12 ± 11,82 |
|------------------------|-------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| n= 5, TAF/FTC/DRV/COBI | Viral Suppresion N, (%) | | N=14 (56%) | | N=21 (84%) | | N=23 (92%) |
| BIC/TAF/FTC | CD4/CD8 | 0,51 ± 0,30 | | 0,62 ± 0,34 | 0,69 ± 0,35 | 0,78 ± 0,37 | 0,88 ± 0,40 |
| Conclusions | | | | | | | |

The results of the present study indicate that BIC/TAF/FTC could improve the immunological response of PWH and limit the dimensions of persistent LLV reducing the risk of VF and drug resistance issues. Further studies in larger patient series are needed in order to determine this beneficial role of Bictegravir.